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510(k) Summary of Safety and Effectiveness
Medical Scientific Corporation
Spyglass Irrigation System
June 27, 2007

1. Sponsor Name

Sponsor/Manufacturer:
Medical Scientific Corporation
125 John Hancock Blvd
Taunton, MA 02780
Tel: 508 880 7313
Fax: 508 880 7347

2. Device Name

Proprietary Name: Spyglass Irrigation System
Common/Usual Name: Endoscope and accessories

Panel: Gastroenterology and Urology
Product Code: KOG

3. Identification of Predicate or Legally Marketed Device

4. Device Description

Spyglass is an irrigation system for Endoscopy. This system is a peristaltic pump for delivering sterile water or saline through an endoscope (or catheter) for rinsing substances such as blood or bile from the procedural site. It is intended for open and endoscopic procedures.

The system is compromised of a pump, foot pedal, and power cord. The connection of the pumping unit to the foot pedal and fluid supply provides the user with a system capable of producing a broad range of pressures. This is based on a variable motor RPM. The motor is controlled by the use of a potentiometer and control dial. An electrically activated foot pedal controls the, running or stopping of the pump motor. The footswitch provide continuous flow when pressed.

5. Intended Use

To provide irrigation during endoscopic surgical procedures

6. Comparison of Technological Characteristics

The comparison of Intended Use, System Components, Flow rate adjustments, Min/max flow rate, Min/max Pressures, and Pump Type indicate the device is substantially equivalent to its predicate.

7 Performance Testing

Bench testing was performed to demonstrate that the Spyglass Irrigation would perform as intended.

8. Statement of Equivalency

The Spyglass Irrigation System is substantially equivalent to the predicate devices. The intended use, technological characteristics of the materials and processes used in the application and safety characteristics of the Spyglass Irrigation System support the concept of substantial equivalence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 18 2007

Paul Nardella, Jr.
President
Medical Scientific Corporation
Taunton Corporate Center
125 John Hancock Road
TAUNTON MA 02780

Re: K071832
Trade/Device Name: Modification to the SpyGlass™ Irrigation System
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LJH
Dated: August 17, 2007
Received: August 30, 2007

Dear Mr. Nardella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K071832
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510(k) Number (if known): K071832

Device Name: Spyglass Irrigation System

Indications For Use:

To provide irrigation during endoscopic surgical procedures

Prescription Use ___X_____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071832